EnCor Breast Biopsy System

ENCSYS-US, ENCSYS-MR, ENCSYS-STL, ENCSYS-STF

Operator’s Manual

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1. INTRODUCTION

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

DESCRIPTION

The SenoRx EnCor System is designed to provide control operations for specialized SenoRx diagnostic and surgical devices. The EnCor System includes:

- Control Module (CM 3000)
- Vacuum System (VS 3000)
- Cart (CART01)

The Control Module provides interface between Drivers and the Vacuum System. SenoRx Biopsy Probes, Vacuum Tube Sets, Canisters, and accessories are available separately.

The EnCor System is designed to recognize individual SenoRx Devices and provide interface, motor speed control, physician feedback, and to accept inputs when used for specific procedures. Each SenoRx Device performs unique functions.

INTENDED USE

The EnCor Breast Biopsy System is indicated to acquire tissue for diagnostic sampling of breast abnormalities. The instrument is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

CONTRAINDICATIONS

This device is not intended for use except as indicated. In addition, it is not intended for use under conditions where breast tissue excision is contraindicated.

WARNINGS

Warning: The EnCor System must be properly grounded to ensure patient safety, and is supplied with a medical grade power cord with AC plug. Do not connect the power cord to extension cords or three-prong to two-prong adapters.

Warning: To minimize interference with other equipment, leads or cables should be positioned to prevent contact with other leads.

Warning: Only SenoRx accessories can be used with the EnCor System. Potentially hazardous conditions may exist if non-SenoRx accessories are used.

Warning: Do not remove covers. Removing covers may cause electrical shock. Contact SenoRx for service.

Warning: In service or operation area – sound levels for generated tones are to be measured when standing in front of the Control Module enclosure.

Warning: The CART01 with equipment installed is stable on a slope of up to 10°.

PRECAUTIONS

***Caution*:** This equipment is intended for use by qualified personnel only.

Caution: Locate the SenoRx EnCor System as far as possible from other electronic equipment to minimize interference.

Caution: Inspect accessories and cords for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or to the operator.

***Caution*:** Inspect tubing connections to the vacuum canister and the disposable tubing set to ensure proper vacuum levels are achieved and maintained during use.

***Caution*:** Inspect the Vacuum Canister to insure no damage has occurred during shipping or installation. A heavily scratched canister can break during use.

***Caution*:** Do not leave the EnCor System powered on overnight. Damage may occur to the tubing set.

Caution: Connect the power cord to a Hospital Grade wall outlet having the correct voltage or product damage may result.

2. ENVIRONMENTAL AND TECHNICAL INFORMATION

ENVIRONMENTAL

Required Conditions for Operation

Ambient temperature	15° - 35° C (59° - 95° F)
Relative humidity	30% - 75%, non-condensing
Atmospheric pressure	700 - 1060 millibar

Required Conditions for Storage

Ambient temperature	-40° - 70° C (-40° - 158° F)
Relative humidity	10% - 95%, non-condensing, STP
Atmospheric pressure	500 - 1060 millibar

TECHNICAL INFORMATION

Class	Class 1 – Connection to a protective earth conductor
Type	BF defibrillation-proof Patient applied part
Category	Not AP or APG, not to be used near flammable gases
Disinfection	Wipe down of enclosure using a disinfectant
Ingress of Water	Ordinary Equipment
Operation	Continuous operation
EnCor System Power:	
Maximum Ratings	100 – 120 VAC 10A, 50/60 Hz, 3-wire, grounded with removable power cord 220 – 240VAC 5A, 50/60 Hz, 3-wire, grounded with removable power cord

Nominal Ratings — Standby (Ready for biopsy)

Voltage/Frequency	115 VAC/60 Hz	230 VAC/50 Hz
Current	0.65 A	0.54 A
VA (Calculated)	74.8	124.2
Watts	63	71
Power factor	0.856	0.571

Nominal Ratings — Operating (Ready for biopsy)

Voltage/Frequency	115 VAC/60 Hz	230 VAC/50 Hz
Current	6.89 A	3.81 A
VA (Calculated)	792.4	876.3
Watts	741	729
Power factor	0.950	0.833

EnCor System Dimensions	16” Wide x 34” Deep x 48” High (40.64 cm x 86.4 cm x 121.92 cm)
EnCor System Weight	155 lb (70.3 Kg)

3. UNPACKING INSTRUCTIONS

Thoroughly inspect the packaging materials and the EnCor System for any signs of transit damage. Do not use the unit if it appears to have any damage. Contact SenoRx Customer Service for instructions on how to report shipping damage.

CART

Carefully unpack and remove contents.

VACUUM SYSTEM

Carefully unpack and remove Vacuum System.

CONTROL MODULE

Carefully unpack and remove Control Module.

SEPARATELY PACKAGED ACCESSORIES

1 AC Power Cord (SenoRx PC3100)

1 18” AC Power Jumper Cord (SenoRx PC3150-002)

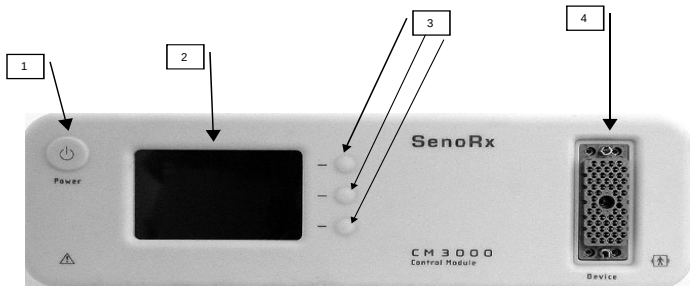
1 53” AC Power Jumper Cord (SenoRx PC3150-003)

1 Footswitch (SenoRx FS ENCOR01)

1 Control Module to Vacuum System Cable (SenoRx CB3100)

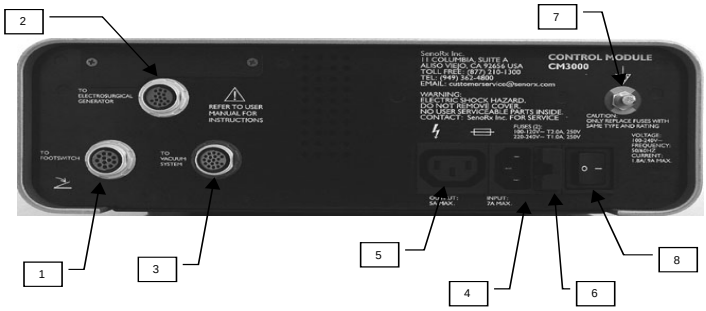
4. COMPONENT LAYOUT AND CONTROLS

FRONT PANEL DISPLAY AND CONTROLS



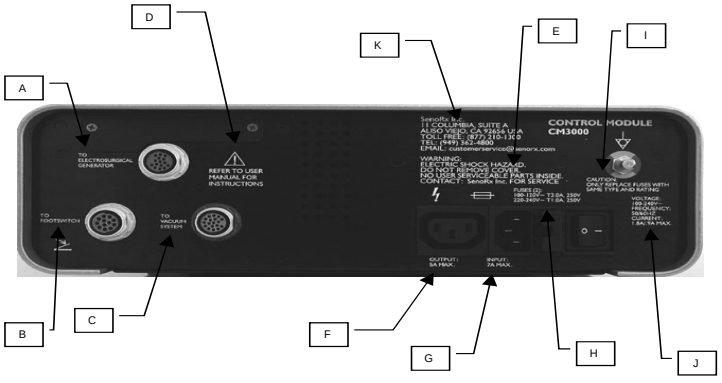
1 Power On/Off
2 Display
3 Selection Push Buttons
4 SenoRx Device Connector

REAR PANEL CONNECTIONS AND CONTROLS



1 Footswitch Connector
2 Not Used
3 Vacuum System Connector
4 Power Inlet Connector
5 Power Outlet Connector
6 Fuse Holder
7 Equipotential Stud
8 Main Power On/Off

REAR PANEL TEXT



A To SenoRx accessories
B To footswitch
C To vacuum system
D Refer to user manual for instructions
E Warning:
F Output: 5a max
G Input: 7a max
H Fuses (2): 100-120v ~ t2.0a, 250v
220 – 240v ~ t1.0a, 250v
I Caution: only replace fuses with same type and rating
J voltage: 100-240v, frequency: 50/60 Hz, current: 1.8a/.9a max

VACUUM SYSTEM

Rear Panel

POWER Switch	Primary on/off control

Front Panel

When active, front panel indicators illuminate as follows:

POWER	Green
VACUUM READY	Green

5. INITIAL SET-UP INSTRUCTIONS

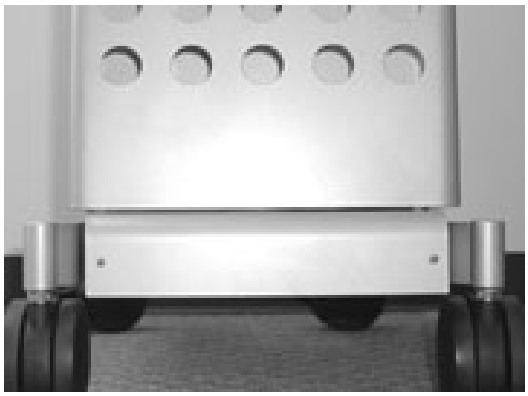
Tools Required:

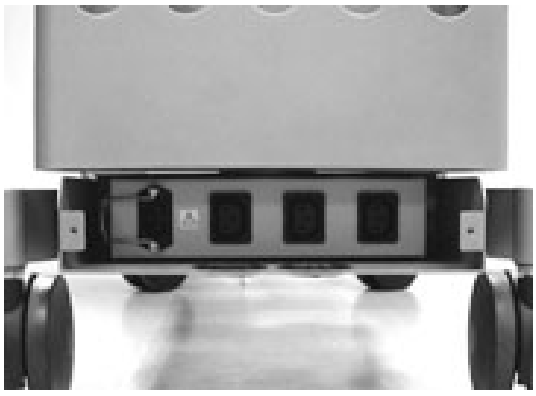
- 5/64” Allen Key (Supplied)
- 5/32” Allen Key (Supplied)
- Screwdriver, Phillips (Not Supplied)

Supplied Hardware

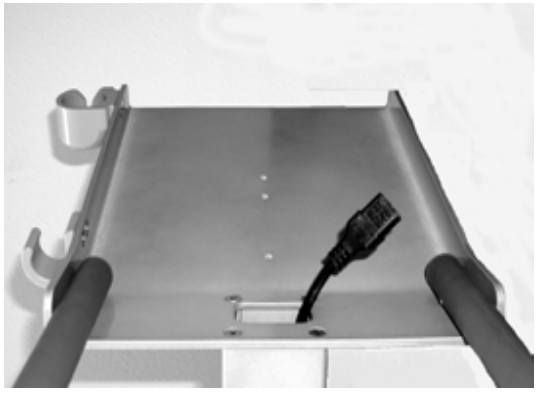
Qty.	Description
2	¼ - 20 x ½” Flat Head Socket Screw
2	¼-20 x 5/8” Flat Head Socket Screw
1	¼ - 20 x ¾” Flat Head Socket Screw
5	¼” Conical Lock Washer
2	¼ - 20 x 1 ¼” Button Head Cap Screw
2	¼” Flat Washers
2	¼” Internal Tooth Lock Washer

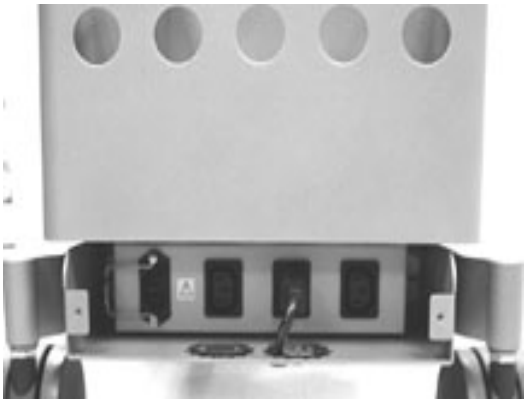
1. Remove Cart, Vacuum System, and Control Module from packing.
2. Remove the power strip cover at the base of the Cart by removing the two screws. Set the cover and screws aside for later re-installation.





3. Route the male end of the 53” Power Jumper Cord from the top shelf of the cart through the Cart’s hollow center post down to the power strip. On the top shelf, temporarily secure the Female end of the Jumper Cord with tape to prevent it from falling down into the post.
4. Route the Male end of the cord up through the right-side oval hole in the bottom of the Power Strip Box. Connect the Male end to the nearest socket in the power strip.

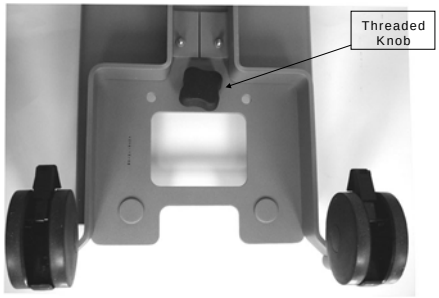




5. Verify that the Vacuum System’s voltage setting by looking at the window on the Input Power Module. If required, refer to the Vacuum System section to change the voltage setting. Verify that the Power Switch is in the “Off” position.

6. Carefully lift the Vacuum System and place onto the bottom shelf of the Cart.

7. Secure the Vacuum System to the Cart shelf by aligning the knob's threads with the single threaded insert centered in the bottom of the Vacuum System. Tighten the knob hand tight, securing it to the Cart.



Vacuum System
Installation Method A

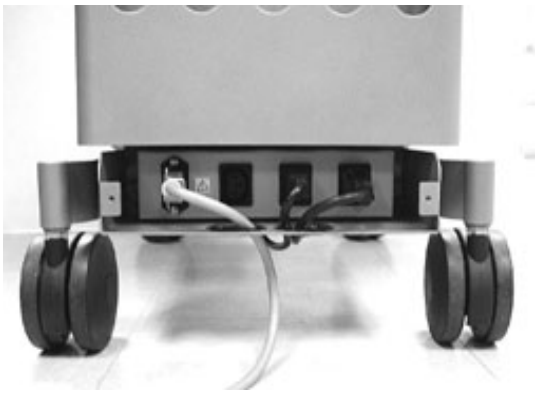
8. Place the Control Module onto the top Shelf of the Cart and align the hole in the Cart with the threaded hole in the Control Module then attach it to the Cart using a ¼ - 20 x ¾" Flat Head Socket Screw and a ¼" conical lock washer.

9. Ensure that the Control Module Main Power Switch is in the "Off" position. Attach the Female end of the 53" Power Jumper Cord routed up through the center post of the Cart to the Power Inlet Connector on the Rear Panel of the Control Module.
10. At the Power Strip Box, route the 18" Power Jumper Cord from the power strip through a hole in the bottom of the Power Strip Box to the Input Power Module of the Vacuum System.

11. Connect either end of the Vacuum System to Control Module Cable to the blue-banded connector labeled “Vacuum System” on the rear of the Control Module. Route the remaining end down through the center post of the Cart. Guide the end of the Cable out through the hole in the side of the center post of the Cart. Connect the other end to the blue-banded connector marked “Control Module” on the rear of the Vacuum System.

12. Connect the Footswitch to the connector labeled “Footswitch” on the rear of the Control Module.

13. Route the Female end of the gray Power Cord from under the Power Strip Box and up through the left side oval hole on the bottom of the Power Strip Box. Connect it to the left-most Power Strip Connector and secure with the wire latch.



14. Replace the Power Strip Cover using the previously removed screws to complete the equipment installation.
15. Connect the gray Power Cord from the Cart only to Hospital Grade grounded wall outlets of the correct supply voltage.

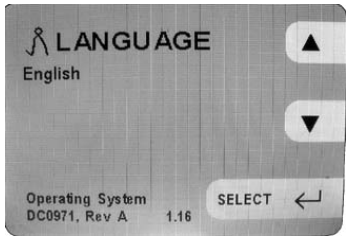
6. CONTROL MODULE – SCREEN DESCRIPTIONS

SCREEN DESCRIPTIONS

Startup Screen

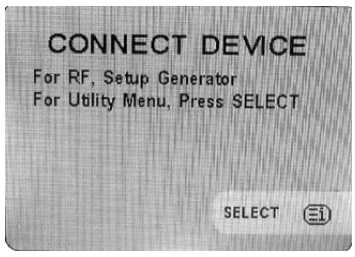
While the Control Module initializes, the SenoRx logo is displayed on the screen

Language Screen



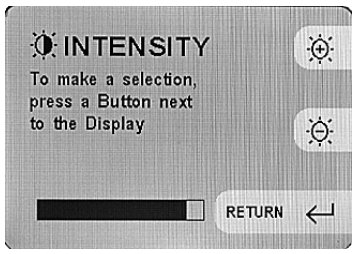
The language screen is accessed during Power Up. For complete instructions on accessing the language screen, see the Operating Instructions – Accessing the Language Screen Section.

Connect Device Screen



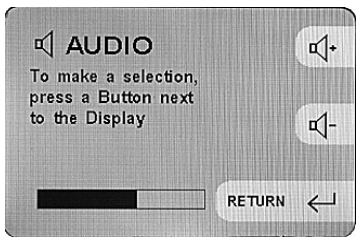
Following initialization, the Connect Device screen displays. While this screen is active, connect a Device. For additional options, press the bottom button to the right of the display on the Front Panel of the Control Module.

Intensity Adjust



Adjust the display intensity brighter or dimmer using the corresponding buttons to the right of the screen icons on the Front Panel of the Control Module. Press the lower right button (Return) to return to the previous screen.

Audio Adjust



Adjust the audio volume louder or softer using the corresponding buttons to the right of the screen icons on the Front Panel of the Control Module. Press the lower right button (Return) to return to the previous screen.

Device Detected

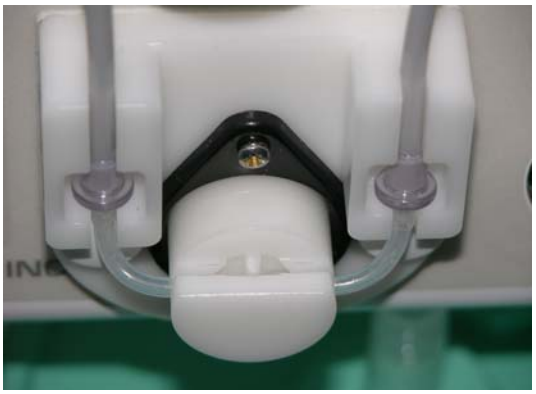
This screen displays acknowledgement from the Control Module that a SenoRx Device is connected, and indicates that the Script for the individual Device is loading.

7. OPERATING INSTRUCTIONS

Vacuum System Set-up

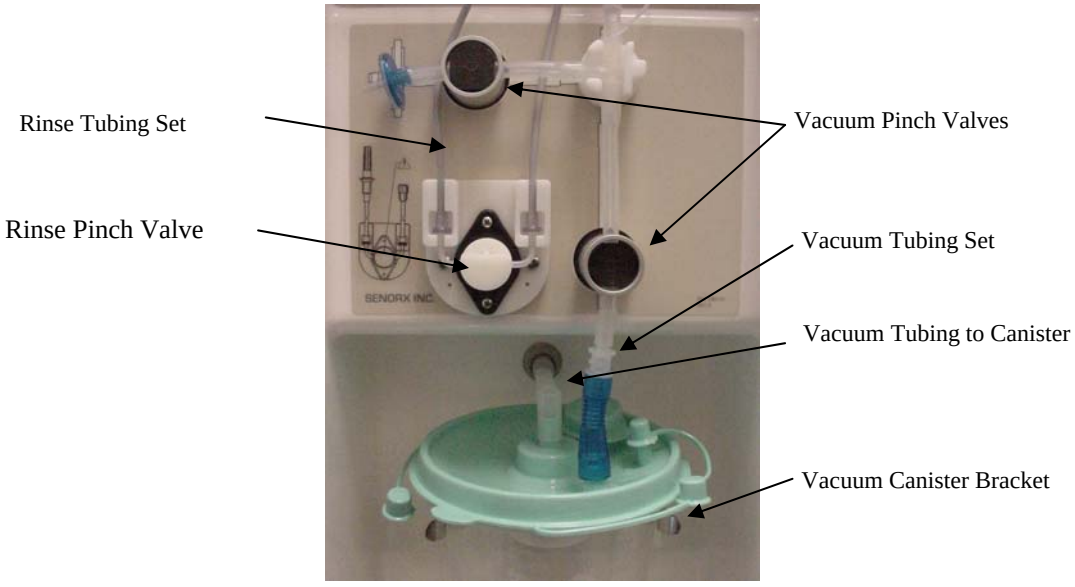
1. Position the EnCor System as required for safe use and plug the Power Cord from the Cart into a Hospital Grade wall outlet.
2. Verify that the Vacuum System pinch valves are free of any debris which may inhibit proper function. Install the Canister, Rinse Tube Set and Vacuum Tube Set as shown in the following pictures.
3. All Canister connections must be securely made or a decrease in available vacuum and alarm conditions may result. Verify that the lid is securely snapped onto the Canister Base and that all unused lid port caps are pressed firmly over the unused ports. Place the Canister into the Vacuum System and securely attach the center port.

4. If using the Rinse feature, install a new Rinse Valve Tube Set and Saline Bag by holding the Rinse Valve Tube Set with the saline bag connector in the left hand and the Probe Tube Set connector in the right hand. Line up the black mark on the Rinse Tube Set with the center pinch bar of the Rinse Valve. Pull the Rinse Tube Set down into the Rinse Valve slot until all of the tubing slides down into the Rinse Valve. Connect the saline bag connector (left side of installed Rinse Valve Tube Set) to the saline bag which can be placed into the upper shelf within the Vacuum System.



5. Install the Vacuum Tube Set:

6. The finished installation should look like:



Probe Tubing Connection to Vacuum System

7. Connect the Probe Tube Set to the Vacuum Tube Set as follows:

8. Connect the Probe Tube Set to the Rinse Tube Set as follows:

Control Module Driver Connection

9. Turn on the power on the rear of the Vacuum System and Control Module.
10. Connect the appropriate Device Driver to the rectangular connector on the front of the Control Module.

11. Follow the Control Module screen prompts. Calibrate the biopsy disposable.
12. "Vacuum Ready" light should be illuminated indicating correct vacuum level has been achieved to initiate biopsy procedure. Vacuum Ready light will only illuminate if biopsy disposable is installed and calibrated. If the "Vacuum Ready" light does not illuminate check all tubing connections and vacuum canister connections to insure correct installation. .

Operation

13. For Handheld Accessory Devices follow the specific Instructions for Use included with each accessory.

    Note: If the system fails during use, check rear panel for blown fuse. Replace as needed.

14. After Use

    Remove disposables and discard per your facilities procedures. Clean and disinfect per the instruction located under the cleaning and disinfecting section.

    The Device may be left connected to the Control Module if similar procedures are to be performed.

    Turn the power switches on the rear of the Vacuum System and the Control Module to the "Off" position.

Accessing the Language Screen

The language screen can only be accessed during Power Up. From the "Off" state, press and release the top left (Power) button on the Front Panel of the Control Module, then quickly press and hold any the top two buttons to the right of the display on the Front Panel. Language selections are scrolled through using the up and down buttons as indicated on the display. To select any language when it is displayed, press the bottom button (Select) to select that language and return to the Main Screen.

Alarm Conditions and Troubleshooting

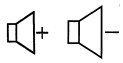
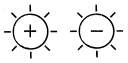
The Control Module is programmed to attempt to determine a reason for any alarm condition that occurs. If the Control Module can find a cause for an alarm, the information is displayed on the display screen.

Depending on the cause of the alarm, different scenarios are required to clear the alarm. Certain alarm causes, when corrected, allow the Control Module to recover automatically, and return to a ready state. Other alarms require pressing a button as indicated on the Display of the Control Module to clear. If a SenoRx Device is connected and is the cause of the alarm, follow the specific IFU for that Device to clear the alarm.

When no other actions are indicated, clear any major alarm condition by first turning off main power using the switch on the Rear Panel. Wait 20 seconds, and turn the main power back on, and restart the Control Module with the Front Panel Power button.

If any alarm condition persists after correcting known problems and clearing the alarm condition from the screen, contact SenoRx for service.

8. SYMBOL DEFINITIONS

Symbol	Description	Symbol	Description
	Attention: Refer to Instructions for Use for instructions		Loudspeaker, Increase or Decrease
	Dangerous Voltage		Footswitch
	Protective earth		Equipotential
	On		Fuse
	Off		Brightness, Increase or Decrease
	Up, increase		Brightness/Contrast
	Down, decrease		Main index page
	Operator		Return or select

Packaging Symbols:

	Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive 93/42/EEC.		
	Relative humidity: Moisture content		Keep away from heat
	Fragile: Handle with care		This way up
	Temperature limitation		Do not dispose of the EnCor System by placing into trash receptacles.
	Contents		

9. CLEANING AND DISINFECTING

To clean the EnCor System, turn off Power and disconnect the power cord from the AC outlet. Leave all other cables connected. Clean all exposed surfaces of the EnCor System, cables, and Footswitch with a soft, lint-free cloth dampened with a cleaning solution or disinfectant. Follow the procedures approved by your institution or use a validated infection control procedure.

Do not use abrasive cleaners or spray any cleaner directly onto any part of the EnCor System or cables.

DISPOSAL OF EQUIPMENT

After following the cleaning recommendations above, there are no risks involved with the disposal of the EnCor System or any of the reusable accessories at the end of the EnCor System's useable life per Waste of Electrical and Electronic Equipment (WEEE) directive [Directive 2002/96/EC]. Dispose of any single use device per the Instructions for Use for the disposable device.

Do not dispose of the EnCor System by placing into trash receptacles.

10. ROUTINE MAINTENANCE

Electrical safety testing should be performed at intervals no greater than 12 months, using a standard medical safety analyzer.

Regularly inspect all cables and connectors for possible wear or damage.

Control Module and Vacuum System have no calibrations or adjustments necessary. All servicing of the Control Module and the Vacuum System should be referred to SenoRx.

Air Filter Cleaning and Odor Control Filter Replacement

Turn the Power Switch to "Off" at the bottom right rear of the Vacuum System.

Air Filter Cleaning:

Using a small flat blade screwdriver, carefully pry the rectangular Air Filter Grill off of the Fan (located to the right of the Odor Control Filter). Remove the Air Filter and wash it using water then dry with a paper towel. Place the Air Filter back into the Air Filter Grill and snap back onto the Fan.

Odor Control Filter Replacement:

Remove the old Odor Control Filter by rotating it counter-clockwise and discard. Install the new Odor Control Filter (SenoRx F3000) by rotating clockwise until snug.

Fuse Replacement and Voltage Selection

Control Module:

The Fuse Holder is accessible after the Power Cord is removed. Unplug the EnCor System from the wall outlet, and remove the Power Cord from the Power Inlet Connector on the Rear Panel of the Control Module, taking precautions to ensure that the Power Cord does not drop down into the center post of the Cart. Using a small slotted screwdriver, press the release tab located near the center of the fuse holder. Pull the fuse holder assembly outward to remove it. The only Control Module requirement for selecting the Voltage is to replace the fuses. Remove and replace any blown fuses per list below in the Fuse Holder assembly, and snap it back into place. Reconnect the Power Cord to the Power Inlet Connector.

For 100-120 V~: 5x20mm, 2A, Time Delay, 250V - Replacement Fuse Kit: Ref. Model No. FK0120

For 220-240 V~: 5X20 mm, 1A, Time Delay, 250V - Replacement Fuse Kit: Ref. Model No. FK2230

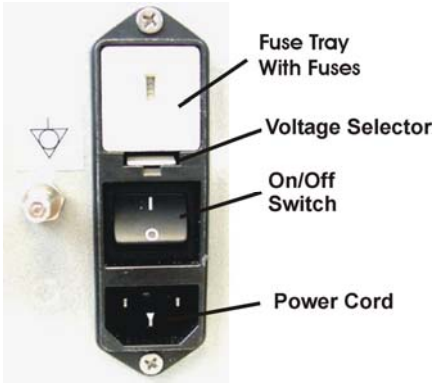
Vacuum System:

The Fuse Holder is accessible after the Power Cord is removed. Unplug the Vacuum System from the Cart power strip, and remove the Power Cord from the Power receptacle on the Rear Panel of the Vacuum System. Using a small slotted screwdriver, push up the release tab located near the center of the fuse holder. Pull the fuse holder assembly outward to remove it from the Power Inlet Connector. If changing the Vacuum System Voltage, also remove the Voltage Selector, select the new Voltage and re-insert the Voltage Selector so that the desired Voltage is visible. Remove and replace any blown fuses per list below in the Fuse Holder assembly, and snap it back into place.

For 100-120 V~: 3AG, ¼ X1 ¼ inch, 8A, Slow Blow, 250V - Replacement Fuse Kit: Ref. Model No. FK1120

For 220-240 V~: 5X20 mm, 5A, Time Delay, 250V - Replacement Fuse Kit: Ref. Model No. FK1240

If converting from 100-120 V~ operation to 220-240 V~ operation, use Fuse Kit Model No. FK0230.



11. CONFORMANCE TO STANDARDS

The EnCor System has been tested to and meets the following standards:

UL 60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety
IEC 60601-1-2 (2001)	Medical electrical equipment, Part 1, General requirements for safety; 2. Collateral Standard: Electromagnetic compatibility-Requirements and Tests
CAN/CSA C22.1 No. 601-M90 including Amendment 1 & 2	General Requirements for Safety

12. WARRANTY

Returned Goods

Returned goods will be accepted only with prior authorization by SenoRx Customer Service who will issue a Returned Goods Authorization (RGA) number. Returned items must be in original, unopened SenoRx cartons in saleable condition and must be accompanied by the RGA number which has been written on the outside of the shipping box. Product shipped or ordered in error must be returned within 90 days from original receipt of order. Outdated products are not returnable. Credit will be issued only for items returned with SenoRx approval.

Damaged Goods

Merchandise should be inspected upon delivery and refused at your receiving department if damaged. Notify SenoRx Customer Service within 5 working days of receipt of damaged merchandise. To contact SenoRx concerning product problems call SenoRx Customer Service or your sales representative.

Limited Product Warranty

SenoRx Inc. ("Company") warrants to the Original Purchaser (as defined below) of the Company's instrument that each instrument shall substantially conform to the specifications for such instrument and be substantially free from defects in material and workmanship for the warranty period set forth below and when used as originally intended under normal conditions and in conformity with its directions for use and/or maintenance instructions. The obligation of the Company under this warranty shall be limited to the repair or replacement, each at no charge, at the option of the Company, of the instrument within one year from the date of purchase, as specified on the Original Purchaser's bill of lading, if examination shall disclose to the reasonable satisfaction of the Company that the instrument is non-conforming. The repair or replacement of such instrument shall be the only remedy to the Original Purchaser and the sole and exclusive liability of the Company for breach of this warranty.

Because the Company has no control over the operation, inspection, maintenance, or use of its products after sale and has no control over the selection of patients, this warranty is made in lieu of all other warranties or conditions, expressed or implied, by statute, in any communication or otherwise, regarding the instrument, including, but not limited to, the warranties of merchantability, fitness for a particular purpose, non-infringement and quality (except as set forth above) and all other obligations or liabilities, express or implied, on the part of the Company. The Company neither assumes nor authorizes any other person or entity, or such party's employees or representatives, if applicable, to assume for it any other warranties, conditions or liabilities, express or implied, by statute or in any communication, regarding the instrument, in connection with the sale or use of the Company's instrument.

This warranty shall not apply to: (i) a Company's instrument or any part thereof which has been subject to negligence, improper maintenance, alteration, modification, abuse, misuse, acts of nature, vandalism, burglary and/or theft, unusual physical or electrical stress, or accident or (ii) a Company's instrument or any part thereof which has been repaired, modified or altered by anyone other than the Company. The Company makes no warranties whatsoever, either express or implied, with regard to accessories or parts used in conjunction with the Company's instrument that are not supplied and manufactured by the Company. The term "Original Purchaser," as used in this

warranty, shall be deemed to mean that person or entity, or their employees or representatives, if applicable, to which the Company's instrument was first sold by the Company. This warranty may not be assigned or transferred in any manner.

In no event shall the company be liable to the original purchaser or any third party for lost profits or any special, consequential, incidental or indirect damages for breach of this warranty. This limitation shall apply even where the company has been advised of the possibility of such damage and notwithstanding the failure of essential purpose of any limited remedy stated herein.

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